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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION O

RESIDUE CHEMISTRY

by

Richard D. Schmitt, Ph.D.

Hazard Evaluation Division
Office of Pesticide Programs

Guidelines Coordinator
Robert K. Hitch
Hazard Evaluation Division
Office of Pesticide Programs

U.S. Environmental Protection Agency
Office of Pesticide and Toxic Substances
Washington, D.C. 20460

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As a guideline for the Federal Food, Drug and Cosmetic Act (FFDCA) and the FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA), Subdivision O describes the data needed for pesticide uses that may result in residues in food, feed or tobacco. These data are used to estimate the exposure of the general population to residues in food and to establish and enforce tolerances for pesticide residues in food or feed.

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Foreword

Subdivision O describes protocols which may be used to perform food, feed, or tobacco residue testing to support the registration of pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA) and Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). These data are used to estimate the exposure of the general population to residues in food and to establish and enforce tolerances for pesticide residues in food and feed.

Subdivision O is a non-regulatory companion to 40 CFR Part 158, Data Requirements for Registration. References to requirements established in 40 CFR Part 158 are presented in Subdivision O so that this document can be read as a complete package and so that the protocols may be explained in their proper context.

SUBDIVISION O

RESIDUE CHEMISTRY GUIDELINES

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SUBDIVISION O - § 170 RESIDUE CHEMISTRY GUIDELINES

§ 170-1 Scope of Data Requirements

(a) General. Sections of this subdivision describe the residue chemistry data requirements specified by 40 CFR Part 158 and the Federal Food, Drug and Cosmetic Act (FFDCA) and some other information needed for pesticide uses that may result in residues in food, feed or tobacco. Residue chemistry data are used by the Agency to estimate the exposure of the general population to pesticide residues in food, and for setting and enforcing tolerances for pesticide residues in food or feed.

(b) Petitions for Tolerance. Residue chemistry data for a new use of a pesticide are generally submitted to the Agency in a petition for tolerance as required under Sections 408 or 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). The format, procedures and fees associated with petitions for tolerance are included in Sections 408 and 409 of the FFDCA, and in sections 180.1 to 180.35 of the Code of Federal Regulations (CFR), Title 40.

(c) Minor Changes in Use Pattern. If a minor change in the use pattern or formulation of a currently registered pesticide is requested, the registrant may have to submit additional residue data to demonstrate that the change will not result in residues exceeding the established tolerance. Examples of changes in pesticide use patterns that are likely to require residue studies, and possibly another petition for a new tolerance, include: (1) significant changes in preharvest interval and in postharvest treatment; (2) extension of use patterns to include low volume or ultra low volume (ULV) aerial as well as ground application; (3) alteration of use patterns to include new types of usage; (4) addition of a sticker or extender to the formulation; (5) conversion to a slow-release formulation; (6) use in additional climatic regions; (7) an increase in the application rate; and (8) an increase in the number of applications allowed.

Examples of minor changes that may not require residue studies include: (1) a change in surfactant concentration; (2) substitution of a new but similar surfactant; (3) substitution of one clay diluent for another. Exceptions must be made individually based on a thorough knowledge of the chemistry of the ingredients involved.

Residue data in support of a changed use pattern are normally submitted to the Agency under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) in a form described in CFR 40, Section 162.

(d) Food Use/Non-Food Use Determinations. The term "food" is defined in Section 201(f) of the FFDCA as (1) articles used for

food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such articles. If a pesticide use is likely to result in residues on food, then the use is a food use, a petition for tolerance or exemption is required, and appropriate residue chemistry considerations apply. Non-food uses are those uses that are not likely to yield residues in food. Uses that could result in residues in meat, milk, poultry or eggs are also considered to be food uses.

(e) Tobacco Uses. Use of a pesticide on tobacco does not require a tolerance or an exemption from the requirement to obtain a tolerance. Nonetheless, data are needed to assess the exposure of man to residues on tobacco. The residue chemistry data requirements for tobacco uses are described in this subdivision and such data should be submitted to the Agency using the procedures for submitting data under FIFRA referred to above.

(f) Aquatic Uses. When a pesticide is applied directly to water, data on potential residues in potable water, fish and irrigated crops will be required. Tolerances are not established for potable water, thus data on residues in water are submitted under FIFRA.* Residue limits for potable water will be established under the auspices of the Safe Drinking Water Act (SDWA) when appropriate. Tolerances for fish and/or irrigated crops will be established if appropriate. Thus, if a pesticide is to be applied directly to water, data on residues in fish and/or irrigated crops should be submitted in the form of a petition for tolerance or exemption from tolerance under the FFDCA.

§171-1 List of Requirements. The sections of this subdivision specifying the residue chemistry information and data requirements are as follows:

§171-2 Chemical Identity. (Section A of a petition)

§171-3 Directions for Use. (Section B of a petition)

§171-4 Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Methods Used. (Section D of a petition)

(a) Nature of the residue in plants and livestock

(b) Analytical methods

(c) Magnitude of the residue

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*Federal Register, Vol. 47, No. 115, Tuesday, June 15, 1982, page 25746, Pesticides Applied to Bodies of Water, Proposed Procedural Changes.

(1) General considerations

(2) Design of residue experiments

(3) Meat, milk, poultry and eggs

(4) Potable water, fish and irrigated crops

(5) Food handling establishment uses

§171-5 Practical Methods for Removing the Residue. (Section E of a petition)

§171-6 Proposed Tolerances. (Section F of a petition)

§171-7 Reasonable Grounds in Support of the Petition. (Section G of a petition)

§171-8 Exemptions from the requirement of a tolerance.

(a) Active Ingredients

(b) Inert Ingredients

§171-9 Tolerances for Foreign Uses.

§171-10 Rotational Crop Tolerances.

§171-11 Tobacco Uses.

§171-12 Food Use/Non Food Use Determinations.

(a) Seed treatments

(b) Crops grown for seed

(c) Fallow land

(d) Dormant crop uses

§171-13 Submittal of Analytical Reference Standards.

§171-14 Temporary Tolerance Petitions.

§171-15 Presentation of Data.

§171-16 Translation of Data.

§171-2 Chemical Identity. (Section A of a petition)

(a) Active Ingredients. Data requirements for chemical identity are essentially the same as discussed in § 60-1 of these guidelines, product identity and disclosure of ingredients. In

addition to these data required in the Product Chemistry Subdivision, Section A of the petition should include an assessment of whether any of the impurities will present a residue problem. If an impurity is likely to occur as a significant residue in food/feed, then residue data for the impurity as described in Section 171-4, Section D of a petition, will be required. The determination of whether residue data for an impurity is needed will be based on the impurity stability, toxicity and detectability.

(b) Information Required for Inert Ingredients. Inert ingredients of the formulation should be fully described, including the chemical as well as any trade names. Chemical abstract numbers (CAS) should be included if available. The chemical names should be in the same form as those for inert ingredients cleared under 40 CFR 180.1001 (c), (d) and (e). If only the trade name is known, the petitioner should request that the supplier of the inert ingredient furnish the descriptive information on the nature of the inert ingredient directly to the Environmental Protection Agency. Any inert ingredient that has not yet been cleared should be indicated, and a request for clearance initiated as described in Section 171 8 (b).

§171-3 Directions for Use. (Section B of a petition)

The directions for use are ordinarily contained in specimen labeling submitted concurrently for registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Labeling means the actual label affixed to the container together with circulars or leaflets that may accompany it.

It is important that the proposed use be described concisely to facilitate correlation of the proposed use patterns with the method of application used to obtain residue data. The directions should be stated so as to be readily understood by the user of the product. Where several products or multiple uses are involved in the petition, it is suggested that Section B should contain a summary table of all the uses relating to the proposed tolerance(s). This table should show the crop, dosage range, schedule of applications, formulations to be used, preharvest interval and any other use relevant use limitations.

The following additional points should be observed in specifying the directions for use in adequate detail:

(a) Application directions.

(1) Field and orchard crops.

Application of dusts, sprays, and granular formulations should be expressed in terms of pounds active ingredient per acre. For band or row treatments, it should be clearly stated whether the lbs/A rate refers to the area treated or the entire field. In the case of full coverage sprays, as for orchards, the dosage should also be expressed as pounds active ingredient per 100 gallons spray solution to runoff, because of the large variation in the number of pounds per acre needed for small trees versus large trees. The quantity of pesticide applied per acre for concentrate orchard sprays should also be related to tree size, usually by specifying the same or less active ingredient as that which would be applied using a full coverage spray. For special modes of application (aircraft, ULV, mist sprays), the directions for use should include both the spray concentration and the spray volume per acre. The names and quantities of any stickers, spreaders, or other adjuvants used in the spray solution should be given. The maximum number of applications allowed, the minimum interval between application and harvest (PHI), and the minimum interval between treatments should be indicated.

(2) Animal treatments.

Animal treatments present special dosage control problems. The concentration of pesticide in the working solution is the primary consideration in dips and wetting sprays. The directions for dips should include some instructions for recharging and maintaining a constant solution strength in the dip tank, and for the disposal of spent dip solutions. Any factors which may affect the deposition of residues should be covered in the directions for use, e.g., the maximum number of retreatments, time of the animal in the dip tank, nozzle type, pressure, or delivery rate of sprays, and the amount of solution to be applied per animal for "pour-on" or other specialized treatments.

When application of pesticides by automatic devices (i.e., photoelectric or treadle actuated sprays) or backrubbers is proposed, the directions for use should take into consideration such factors as how often they should be recharged and where they are to be placed so that the degree of exposure of the animals may be gauged.

(3) Fumigants.

Dosages may be expressed in terms of weight of fumigant per volume of storage space (lbs act/100 ft^3) or, where appropriate, weight of fumigant per unit weight of commodity treated (lbs act/1000 lbs grain).

Parameters such as time of exposure, temperature, pressure, geometry and airtightness of containers, and aeration procedures (including time of aeration) should be specified.

(4) Aquatic uses.

The application of a pesticide to flowing water, impounded water, irrigation ditch banks, dry beds of water conveyance systems, or other aquatic sites is termed an aquatic use.

The types of application will vary widely, depending on the mode of action of the pesticide. Herbicides for deep growing submersed weeds may require deposition of slow release granules on the bottom near the root zone. For this type of treatment, the dosage would be expressed in terms of lbs act ingredient per surface acre, much like an agricultural field use. The use of a water-soluble herbicide which acts by direct absorption into the target plant is dependent on maintaining a certain concentration in the water and the dosage should be expressed in terms of ppm in water. In the latter case, the directions for use must relate the dosage per surface acre to average pond depth.

Aquatic herbicide applications may require some very specialized equipment. A detailed description of the equipment and principles involved in the treatment should be included; for example, metered pumping of invert emulsions to the bottom of lakes through weighted hoses. A proposed use of timed release capsules will require information on how the encapsulated material is placed and the mechanism of the release.

It is frequently necessary to include limitations on the minimum distance from a potable water or irrigation intake pipe. This limitation is necessary whenever unacceptable levels occur in water at the intake pipe.

To avoid loss of desirable species through oxygen depletion, it is sometimes necessary to treat at intervals only portions of ponds with heavy weed infestations. The label should state what proportions of a pond should be treated per application and the required interval between treatments. If treatments are intended only for pond margins, as opposed to overall broadcast treatment, it should be so indicated.

Ditch bank treatments are usually made by boom sprayers from trucks. For adequate coverage, there is an unavoidable overlap with some direct addition to the water as well as runoff contamination. The label should clearly direct how such treatments are to be made with minimum contribution of herbicide to the water. A prohibition may be required against cross-ditch spraying.

(5) Foreign uses.

Tolerances may be proposed to cover residues resulting on food treated in foreign countries so that such foods may be

imported into this country. The pesticide products used in the treatment may be of foreign manufacture, or may be manufactured in the United States and exported to the country where the application is made. Use of a pesticide in a foreign country is of course not registered under FIFRA. Therefore, Section 408(d) of the FFDCA which provides only that registrants under the FIFRA may petition for tolerances, is not applicable. The proponent of a tolerance on imported foods should therefore petition under Section 408(e) of the FFDCA.

For domestic pesticides uses, a determination is made by the Agency that the tolerance is adequate to cover residues likely to result from uses as directed on registered labels. In the case of foreign uses, it is required that the petitioner provide all necessary information on the amount, frequency, and time of application, along with a statement as to what regulatory mechanism is available to control the use in the country of origin.

(6) Food handling establishments.

A Food Additive Regulation set under Section 409 of the FFDCA specifying the conditions of use in food handling establishments shall be a requirement for registration of such a use under FIFRA. The regulation may or may not specify a numerical tolerance for residues in foods.

Although directions for use will ordinarily be contained on the product label, the usage directions for those products intended for use solely by professional pest control operators may be presented as a technical bulletin. The potential for food contamination from treatments in areas where food is prepared or processed rests largely upon the care exercised by the applicator in following the directions and observing specified restrictions. For this reason, the instructions should be explicit. The directions for use should include (for example) the type of establishments that may be treated, the dilution instructions for preparing the working solution, the spray concentration, the type of equipment by which it is to be applied, the mode of application (directed spray to crevices, baseboards, space spray, etc.), dosage limitations including cubic and square foot limitations, frequency of treatment, time of treatment (after-hours in restaurants), and other pertinent information, as: (1) sanitation procedures; (2) removal of food; (3) covering of dishes and utensils; (4) cleanup procedures before food preparation, processing or serving resumes.

(7) Agricultural premises.

Agricultural premise uses will vary widely and might include distribution of granular insecticides to feed lots; fogging of dairy barns; installation of impregnated strips or cords in animal barns; or applications of sugar-base bait sprays to walls,

stanchions, and other surfaces of barns. The directions for use should be sufficiently detailed to permit an evaluation of the potential for residues on milking equipment, exposed feeds, drinking and feed troughs, or in meat, milk, poultry and eggs of animals quartered on treated premises. The directions should state what areas are to be treated, frequency of treatment, whether animals must be removed at time of treatment, and any other pertinent information. Dosage for fogging treatments should be expressed in terms of lbs per unit volume of the structure treated; impregnated strips and similar devices in terms of number of installations per unit volume; sprays in terms of concentration of active ingredient in the solution applied; and feed lot applications in terms of weight of active ingredient per unit area.

(8) Miscellaneous applications

The general criteria for use directions do not apply to certain specialized processes, such as the manufacture of impregnated fruit wraps to control fungus diseases, or processes in which pesticide are applied post-harvest to fruits, such as in a wax coating. Under these circumstances, the user of the pesticide product is a trained operator experienced in the use of relatively complex mechanical equipment, and directions for use on the retail packages are usually not necessary. However, a complete description of the process including quality control measures and directions for disposal of spent dip solutions or runoff should be made a part of Section B of a petition.

(b) Restrictions.

Clearly written and practical uses restrictions are necessary so that the Agency may gauge the residues likely to result. The following are limitations which should be specified when pertinent to the use:

(a) State the maximum number of applications permitted during a growing season together with the timing and the interval between treatments.

(b) Specify the interval between last application and harvest (or slaughter). This may be expressed in terms of days before harvest or may be tied to a stage of crop maturity such as "not after first bolls open." If the directions for use are related to some identifiable growth stage, such as "first bolls open" or "pegging time," the petitioner should indicate the minimum time from this stage to harvest.

(c) Avoid impractical or unrealistic use restrictions. Restrictions against the food or feed uses of plant parts other

than the primary raw agricultural commodity are practical only when the item remains under the control of the grower and the item is not of major economic importance. For example, a restriction against feeding sugar beet tops is practical because the tops remain under control of the grower; a restriction against feeding dried citrus pulp from a treated grove is not practical or acceptable, since the pulp from a treated fruit would not retain its identity in processing. As another example, a restriction against feeding corn forage or fodder is impractical because of the major economic importance of corn forage and fodder. Restrictions of more than 2 days in the time interval between application to animals and slaughter are considered impractical because animals may be sent to slaughter over an extended period of time, and once sold are no longer under control of the user of the pesticide. Table II and the "Guide for Estimating Toxic Residues in Animal Feeds or Diets"* may be consulted for an indication of whether a feed item is under control of the grower.

A restriction calling for discarding of milk during a prolonged interval after the treatment of lactating dairy cattle would be considered unrealistic, since it would impose an economic hardship on the user and would tend to be ignored.

(d) Use restrictions should be as specific as possible. A restriction such as "Do not use after lay-by" is indefinite in that lay-by time for a given crop may vary considerably due to differences in cultural practices and geographical areas. Indefinite terms such as "Do not use on animals being finished for slaughter" should be avoided and a specific withdrawal period should be stated; similarly, withdrawal times after an animal treatment must be practical. Restrictions should also be as inclusive as possible. For example, the warning "Do not use on dairy animals," is preferable to "Do not use on dairy cows," since the latter excludes dairy goats.

In the case of uses in food handling establishments, specific directions to minimize residue transfer are especially important. A general caution such as "Avoid contamination of food" is by itself of limited effectiveness and should be supplemented by explicit warnings such as "Cover food utensils," "Do not apply when exposed food is present," "Apply after plant operations are shut down," or "Wash food contact surfaces before plant resumes operation."

§171-4 Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Methods Used.

(a) Nature of the Residue.

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* Available from the National Technical Information Service (NTIS) as document Number PB-243-748-LK.

(1) Characterization of the Total Terminal Residue.* Many pesticides undergo change during or after application to the soil, water, crop, or livestock. The composition of the terminal residue must therefore be determined before complete residue detection methodology and residue quantification data can be developed.

The use of radiolabeled pesticide compounds usually is the only satisfactory way of providing such metabolism data. In choosing the position to be labeled, assurance is required that a labile position is not chosen. Usually ^{14}C labeling is preferred, although ^{32}P, ^{35}S or other elements may be more appropriate if no carbons or only labile carbon side chains exist in the molecule. Tritium use is strongly discouraged. Ring labeling is preferred for most aromatic or cyclic compounds. If a potentially labile side chain or tritium labeling is chosen, a metabolism study will be considered adequate only if all significant activity in the plant is identified and found to be associated with the pesticide, and not related to loss of the label from the basic structure of the pesticide molecule.

While in vitro data are useful to show if the pesticide is likely to undergo hydrolysis (acid, base, or enzymatic), oxidation or reduction, photolysis, or other changes, additional data must usually be submitted to show the fate in the plants and animals. These metabolism studies are required whenever a pesticide use is determined to be a food use. Based on the results of the characterization studies, the chemical definition of the "total toxic residue" should be proposed. The term "total toxic residue" is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound) and impurities which are of toxicological concern. All components of the "total toxic residue" will be included in the tolerance expression for the pesticide and residue analytical methods must be developed for all components of the "total toxic residue."

The identification of the components of the terminal residues and the definition of the "total toxic residue" often present complex problems that must be resolved before finalizing the analytical methodology and gathering the residue quantification data. Thus, the petitioner may wish to consult with the Agency's chemists and toxicologists to determine whether the residue has been sufficiently characterized, which metabolites should be covered by the tolerances, and which components of the residue must be determined by the residue analytical methodology. The determination of whether the residue has been sufficiently characterized will depend on the level of activity remaining unidentified,

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* The term total terminal residue is used to refer to all components of the residue whether or not they are toxic enough to be of concern.

the importance of the plant or animal tissue containing the unidentified residue as a food or feed, the chemical structure of the active ingredient and identified metabolites, the toxicity of the active ingredient, and the toxicity of chemicals similar in structure to potential metabolites.

The petitioner should delineate, preferably in a flowsheet, the routes of degradation or metabolism in plants and animals; and clearly specify the capability of the analytical method(s) to determine the components of the residue, whether free or bound. Photographs of thin-layer chromatographic (TLC) plates, paper chromatograms, or radio-autographs of plants treated with labeled pesticides should be furnished. Such evidence will contribute significantly to the evaluation of the data.

The petitioner should always be alert to the possibility of new and unexpected metabolites of the pesticide which may affect future tolerance proposals. Where the structure of a metabolite or alteration product is identical to another registered pesticide chemical, the petitioner should state this fact.

(2) Nature of the Residue in Plants.

The term "plant metabolism" is used here for convenience to describe the formation of all alteration products of the pesticide in or on plants regardless of whether they result from plant metabolic processes. Adequate plant metabolism studies fulfill at least four purposes: (1) they provide an estimate of total residues in the treated crops; (2) they identify the major components of the terminal residue, thus indicating the components to be looked for in residue quantification studies; (3) they indicate the distribution of residues, e.g., whether the pesticide is absorbed through roots or foliage, whether translocation occurs, or whether the residues are entirely surface residues; and (4) they show the efficiency of extraction procedures for various components of the residue.

Identification techniques such as co-chromatography with synthesized model compounds, reverse isotope dilution, and mass spectroscopy are often employed for identification of the residue components. Enzymatic, basic, or acid hydrolysis techniques may need to be employed to release bound or conjugated residues. It is important that the need to use these techniques to release the residue is determined and that, if necessary, these techniques are included in the analytical methodology.

The minimum application rate in a plant metabolism study should approximate the proposed label rates; however, exaggerated rate studies may be necessary in order to obtain sufficient activity for identification. The metabolism studies should be carried to plant maturity whenever possible, so that the composition of the residues found is indicative of that in the terminal residues at harvest.

The study should include characterization of the residue in all plant parts used for food or feed. Table II includes a list of the RAC's derived from each crop. A metabolism study must be submitted for each type of plant for which use is proposed. For example, metabolism studies in bean plants would be representative of all legumes but would not be translatable to root crops such as potatoes or carrots. In general, one metabolism study will be required for each of the crop groups defined in CFR 40 180.34(f), except for herbs and spices.

If the results of three metabolism studies on dissimilar crops indicate a similar metabolic route in the three crops, then additional metabolism studies will not be required.

(3) Nature of the Residue in Livestock. The purpose of these studies is to identify the nature of the residue in the edible tissue of livestock, milk and eggs. Animal metabolism studies are required whenever a pesticide is applied directly to livestock, animal premises are to be treated, or residues result in crops or crop parts used for feed. Information on whether crop byproducts are used for feed can be obtained from Table II and the "Guide for Estimating Toxic Residues in Animal Feeds or Diets" cited previously.

Data on the metabolism of a pesticide in laboratory animals which are required in the toxicology section of these guidelines will generally not substitute for metabolism data on livestock. Laboratory animal metabolism studies should, however, be duplicated or referenced in the residue chemistry section of a petition to allow for comparison of the metabolism in several species. In some cases laboratory animal metabolism data may be used to supplement livestock metabolism studies in which complete charaterization of the residue is not attained.

In general, separate metabolism studies are required for ruminants and poultry. The species of choice are usually goats and chickens. Non-ruminant (swine) metabolism studies may be required if the rat metabolism is significantly different than the goat or chicken metabolism. Additional animal metabolism studies are required if direct dermal or inhalation application to livestock is proposed. These additional studies should reflect the proposed use so that it can be determined whether dermal or inhalation exposure results in the same metabolic patterns as oral dosing.

The minimum dosage used in metabolism studies should approximate the level of exposure expected from the feeding of tolerance level residues on crops with existing, proposed or anticipated tolerances, or the proposed use rate for direct animal treatment.

However, exaggerated dosages are usually required to obtain sufficient residue in the tissues for characterization. Animals dosed orally should be dosed daily for at least three days. Direct animal treatment dosing should reflect the proposed use. Animals should not be preconditioned by dosing with unlabeled material. The material fed should simulate the terminal residues in feed items as closely as possible or reflect the material to be used in a direct animal treatment.

Animals should be sacrified within 24 hours of cessation of dosing.

Milk and eggs should be collected twice daily. Tissues to be analyzed should include at least muscle, liver, kidney and fat. Characterization of the residue in urine and feces frequently facilitates characterization of the lower levels of residue found in tissue, but is not required.

The livestock metabolism study should primarily identify the compounds for which analytical methods and residue data must be generated. It should also indicate the distribution of residues in tissues, eggs and milk, and whether residues are stored and accumulated. The livestock metabolism study should also result in elucidation of the efficiency of extraction of the various components of the residue so that extraction/residue release procedures can be developed as part of the analytical methods.

(b) Analytical Methods.

(1) General Requirements.

The methods for residue analyses should serve two functions: (1) they must provide the residue data upon which judgments are made as to the identity and magnitude of residues from the proposed use, and (2) they must provide a means for enforcement of the tolerance. The methods described in the FDA Pesticide Analytical Manual (PAM) and the Official Methods of Analysis of the Association of Official Analytical Chemists can be used as examples of suitable Analytical Methods.

The analytical method(s) must be described in a stepwise fashion in sufficient detail to enable a competent analyst to apply the method even though he is unfamiliar with the procedure. Reprints of published methods may be included in Section D. However, where modifications have been made to adapt a basic method to other crops for which a tolerance is proposed, details of the modifications are needed. This includes application to the byproducts, meat, milk, poultry, or eggs if these are a consideration.

The method should not be subject to substrate-related interferences or those arising from reagents. Appropriate clean-up measures should be incorporated to reduce or eliminate spurious responses that might jeopardize the results. For example, in gas-liquid

chromatographic methods, separation should be sufficiently distinct to yield reasonably discrete peak(s) for the component(s) of interest rather than a response which appears as a shoulder on an interfering peak.

Whenever possible, Gas Liquid Chromatography (GLC) retention times and response values should be reported relative to those of a stable reference compound, particularly when the residue is converted to a derivative prior to gas chromatography. GLC parameters should be reported in a form such as the guidelines outlined in J. Agric. & Food Chem., Vol. 20 No. 6, page 1275; (1972).

(2) Validation of method by petitioner.

Methods must be validated by control sample data and recovery data for all components of the "total toxic residue" on an adequate representation of the commodities involved. Blank values should be reasonably low in relation to the proposed tolerance. Recoveries should be at fortification levels appropriate to the proposed tolerance. Recoveries should be at least 70%, and should not vary signficantly from sample to sample. If 70% recovery is not attainable, the Agency will accept, on a case-by-case basis, methods having lower recoveries for active ingredients that are not acutely toxic or minor metabolites.

The raw agricultural commodity, or a macerate thereof, should be fortified, rather than crop extracts. The portion of the crop to be analyzed is specified in the Pesticide Analytical Manual (PAM) Volume 1,* in 40 CFR 180.1, and in Table II. The petitioner should state his estimate of the practical limit of detection as applied to each of the subject crops or tissues. The estimate of the practical limit of detection should be based on the least concentration of pesticide which can be detected with a reasonable degree of assurance, taking into account the size and variation of blanks (instrument response due to crop extractives and reagents).

(3) Extraction efficiency.

Conventional recovery experiments as discussed above do not necessarily reflect the efficiency with which aged (weathered) residues are extracted from crops. There should be some assurance that aged residues are completely extracted by the procedure.

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*Available from the National Technical Information Service (NTIS) as order number NTISVB118.

Radioisotope labeling provides the best evidence on completeness of extraction; but other techniques, such as comparison with exhaustive extraction procedures, may be used. Frequently this information can be obtained as part of the plant and animal metabolism studies.

Data obtained by surface stripping are not acceptable except for crops where other data on that crop have established that the total residues are in fact only surface residues.

As a general rule, chlorinated hydrocarbon insecticides from watery vegetables should be extracted with a non-polar solvent in combination with a polar solvent. Very dry samples, such as hay, often require the addition of water to the sample as well as the employment of more exhaustive techniques.

Certain components of the residue may occur bound with naturally occurring plant constituents, and thus may not be recovered by extraction techniques that are satisfactory for the free components. Whenever there are indications of the formation of bound components which may not be recovered by the extracting solvent, modifications should be made in the procedure that will free and recover the liberated components. One such modification would be the initial hydrolysis of the treated crop. These bound components may also be recovered with polar solvents and hydrolyzed under acidic, basic, or enzymatic conditions to free the components. These should not be confused with those fragmentary components which may be so tightly bound or incorporated into the plant's metabolic pool that they are not recoverable by any chemical means. Such components are of interest, but are not usually of toxicological concern.

(4) Determination of "total toxic residues."

The method or methods employed should measure the "total toxic residue" found in the metabolism studies outlined in Section 171-4(a), nature of the residue. Often all components of toxicological concern will contain a common chemical moiety so that the method may be adapted to determine all compounds simultaneously. However, in some cases, it may be necessary to adapt separate extraction-cleanup procedures, or even another complete method, to measure the "total toxic residue" or a significant component of the residue. In other cases, one or more components of the residue will be significantly more toxic than other components of the residue and will have to be determined separately.

(5) Requirements for regulatory methods.

One or more of the methods proposed in the petition must be acceptable to enforce the proposed tolerance. Where applicable, use of the FDA multi-detection methodology outlined in Vol. I of the Pesticide Analytical Manual is strongly recommended. Also, the enforcement method should be as simple as possible to decrease the cost of monitoring for pesticide residues.

A method which may be valid for gathering residue data is not necessarily suitable for enforcement purposes. In general, an enforcement method should:

- Not require the use of a sample of the untreated commodity as a blank;
- Not require the use of an internal or procedural standard (such samples are not available to enforcement analysts);
- Not require exotic equipment or reagents (or reagents that are no longer manufactured);
- Be reasonably rapid in execution;*
- Be sufficiently specific to measure and identify the residue in the presence of residues of other pesticides which could reasonably be expected to be present on the same commodity; and
- Be sufficiently sensitive in relation to the tolerance proposed.

Methods based on cholinesterase inhibition are not regarded as suitable for enforcement purposes. Methods based on paper or thinlayer chromatography and which visually measure the residue are not adequately quantitative for enforcement purposes. They may be useful, however, as confirmatory methods to help identify the residue.

Although certain gas-liquid chromatographic detection systems possess inherent specificity, methods based on these systems should

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* Regulatory methods should require a maximum of 24 hours for completion. Methods taking longer than 24 hours will be considered acceptable on a case-by-case basis for minor metabolites or residues that are not acutely toxic. Methods taking less than 24 hours will be required for acutely toxic residues because of the possibility of the enforcement of accidental or misuse contamination.

usually be supplemented by a confirmatory method. In general, confirmation by mass spectrometry is suitable. The specificity may also be enhanced by the use of special extraction-cleanup procedures, derivatization, parallel or alternate columns and p-values.

The method(s) proposed for enforcement may be subjected to trials in EPA laboratories if the pesticide is new, if the analytical method(s) is new and unfamilar, or if the commodity is known to be difficult to analyze. The burden of proof is on the petitioner, and should the method fail to perform as expected in these trials, the petitioner will be asked to resolve the difficulties. Also, the petitioner will be responsible for improving such a method and furnishing new residue data by the improved method. If the method performs satisfactorily and is acceptable as an enforcement method, it will be made available to interested parties by publication or reference in the FDA Pesticide Analytical Manual. Thus, a petition must include a copy of the analytical method which is not claimed to be, or stamped, confidential business information. The Agency will not release copies of the method to the public until the permanent tolerance has been established. Methods will be released to enforcement agencies prior to the establishment of a permanent tolerance if FIFRA Section 18 emergency exemptions or a temporary tolerance is in effect.

(c) Magnitude of the Residue.

(1) General Considerations.

The residue field experiments will basically consist of examination of raw agricultural commodities for residues of the pesticide chemical after treatment corresponding to the uses proposed in Section B of a petition. If the pesticide or its formulation(s) are not from regular production lots, it should be clearly stated how they differ from regular production lots. If the residue studies are carried out prior to availability of a commercial formulation, then only analysis of the technical chemical used in the residue studies and a statement of formula will be required in the petition. These data are needed for comparison to the commercial formulations at the time of registration.

Residue investigations should be specifically designed so as to circumscribe the total residue picture. Data should be available to show whether residues occur on any plant parts that may be used in foods or feeds. Use on rice may necessitate residue data for water, crayfish, catfish, and irrigated crops when water from the rice field is diverted to such uses.

Guidelines for specific areas of consideration are as follows:

(i) Residue(s) determined.

The purpose of field experiments is to quantify by chemical analyses the terminal residues of concern that have been previously demonstrated in the metabolism studies. The "total toxic residue," as defined in Nature of the Residue, should be determined by the chemical method of choice. In some cases, it may be necessary to employ more than one analytical method to determine the "total toxic residue." Terminal residues in some commodities may differ from those found in other commodities, e.g., residues in meat or milk may differ from those in plants. In cases where determination of bound residues or minor metabolites require separate analysis or unduly increase the cost of processing residue samples, not all samples must be analyzed for these components. However, enough of the samples must have been analyzed for these components to allow estimation of the ratio of these components to the parent compound.

(ii) Sampling.

The samples taken should be of the whole raw agricultural commodity (RAC) as it moves in interstate commerce. For some crops there may be more than one RAC derived from the crop. For example the RAC's for field corn include the seed, fodder and forage. Table II contains a list of the RAC's derived from each crop. The sample should not be brushed, stripped, trimmed, or washed except to the extent that these are commercial practices before shipment, or to the extent allowable in Section 180.1(j), Code of Federal Regulations, the PAM or the Codex Document Alinorm 81/24, appendix III. It should be noted that in the enforcement program, produce is examined for residues on an "as is" basis, regardless of whether it meets any Federal or State quality grading standards with respect to washing, brushing, or number of wrapper leaves retained. Because certain crops (cabbage, celery, and lettuce) may be shipped without having been stripped or trimmed, samples of these crop should reflect both trimmed and untrimmed samples; only obviously decomposed outer leaves should be removed. The preparation of each sample prior to analysis should be indicated.

Samples should be collected to reflect the various parts of the commodity that might be marketed separately, consumed or fed at various times. For example, in an early post-planting use on winter wheat, the green plant should be sampled at the time it might be foraged, the mature wheat grain should be sampled, the dried straw should be sampled, and the bran, millings, and flour from the grain should also be analyzed. Table II includes a list of the various RAC's and processed commodities that should be analyzed.

The sample taken from a field should be representative of all portions of the crop from the field. Thus, there should be a valid statistical basis for sampling. Standardized procedures, such as the use of the Latin squares for a forage crop, selection of tree fruits from the upper, middle, and lower levels of opposing quadrants of the tree; the use of grain triers for the taking of core samples of commodities in bulk quantities; and sample reduction by quartering are desirable to assure a representative sampling. While analysis of replicate samples from a field is desirable, it is preferable to have additional field site data rather than replicate data from within a field if only a limited number of samples are analyzed.

Accepted procedure for maintaining sample integrity should be followed after taking the sample. Normally samples should be frozen as soon as possible and kept frozen until analyzed. Information should be furnished on how samples are shipped and stored until analyzed. If samples are likely to be held in storage, storage stability data should be obtained by fortifying control samples, storing them under the same conditions as the treated samples, and analyzing at the end of the storage period. It is always advisable to have spiked storage stability samples available to allow for unforeseen delays in analysis, and to verify the results of analysis of check samples should reanalysis be necessary to verify possibly aberrant results.

(2) Design of residue experiments.

(i) Field studies.

The field experiments should not be considered merely as an adjunct to field performance (efficacy) tests but should be designed specifically to yield residue data. The procedures described in the Food and Agriculture (FAO) Plant Protection Bulletin, Vol. 24, 1981, page 12, should be followed in the design and execution of residue field trials.

Field experiments must reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed. Because of differences observed in residue levels resulting from ultra low volume (ULV) and aerial applications, these too should be represented unless the proposed label specifically prohibits such application methods. Some crops may be grown under conditions of little or no rainfall, such as lettuce grown in the Imperial valley of California. The label (Section B) should contain a restriction against the use on such irrigated crops unless data are provided for crops grown under these conditions.

The locations of the field experiments should reflect all of the principal growing regions of the crop as indicated in the annual USDA publication Agricultural Statistics, even if no pest

pressure currently exists in some of the major growing areas. Seasonal variations in the production of crops should also be represented. These should include an arid region where the crop is grown by furrow irrigation and residues are likely to be high. Several varieties should be represented, and cultural practices for the crop should be followed. For minor crops, the amount of geographical representation needed may be limited if the registered label limits the geographical area where the product may be used.

The field experiments must also provide for residue dissipation or decline studies in which samples are taken at intervals during the period from the last application of the pesticide to normal harvest. The data obtained should indicate the pattern of uptake of the pesticide and its decline. When presented graphically, these data are useful in determining a preharvest interval if one is needed. Data on the decline of residues after harvest are also desirable. These data are used by the enforcement agencies following accidental contamination or misuse.

There are no specific requirements as to the number of field experiments or of individual samples. Because variations in residue values are always to be expected, the number of samples should be sufficient to give assurance that the proposed tolerance can be met. Usually, the more widespread and important the crop, the more field experiments and samples are required. Similarly, if there is a great deal of concern over the toxicity of the residue, then more field experiments and samples will be required to give the needed assurance. Replicate treatment of individual sites is usually not necessary since variations in residue levels within a field are usually small compared to the variation between sites.

(ii) Fumigation uses.

In addition to treatments at the proposed use conditions, treatment at exaggerated rates is desirable. The studies should adequately represent those commodities which might be treated, including oily foods (peanuts, butter), and high surface area foods (flour), and types of packaging allowable under the directions for use. The studies should reflect the effect of parameters such as time of exposure, dosage, temperature, pressure, geometry and airtightness of the container upon residue levels. The effect of aeration time and procedure upon residue reduction should be demonstrated.

(iii) Slow-release encapsulated formulation uses.

The use of slow-release encapsulated formulations may lead to higher residues than conventional formulations. Thus, if use of a slow-release formulation is proposed, residue data reflecting this formulation will be required. Data showing that the analytical method detects any active ingredient remaining in the encapsulating

material at the time of analysis is required. The registrant should consult the Agency chemists and toxicologists concerning whether residue data on the encapsulating wall material are needed. The general criteria used by the Agency is that if the encapsulating material is an inert polymer and is not absorbed from the gut, then residue data are not required. For polymers not previously cleared, this requires a radiolabeled encapsulating material feeding study with rats showing essentially 100% excretion of activity, with no residual activity in tissues. Data on the residue levels of the encapsulating material will not be required for uses involving application before edible parts form.

(iv) Processed Food/Feed Studies.

(a) Concentration of Residues on Processing.

Whenever there is a possibility of residue levels in processed foods/feeds exceeding the level in a raw agricultural commodity (RAC), processing data are required. Examples of processed foods/feeds in which residues may concentrate are apple juice, wet and dry apple pomace; the hulls, meal, crude and refined oil and soapstock from cottonseed; or the sugar, dried pulp and molasses from sugar beet roots.

A list of processed byproducts is contained in Table II.

Processing studies must simulate commercial practices as closely as possible. RAC samples used in processing studies must contain field-treated detectable residues, preferably at or near the proposed tolerance level, so that concentration factors for the various byproducts can be determined. This may require field treatment at exaggerated application rates to obtain sufficient residue levels for processing studies. Processing studies utilizing spiked samples are not acceptable, unless it can be demonstrated that the RAC residue consists entirely of a surface residue.

If the processing studies indicate that residues concentrate on processing, then a Food Additive Petition, including a Food Additive Regulations proposal, is required. If the processing of the RAC may result in alteration of the residue, then a radiolabeled processing study to determine the nature of the residue in food/feed as consumed may be needed. If significant alteration of the residue occurs, and the additional residue components are of toxicological concern, then the Food Additive Regulation must include the additional residue components.

(b) Reduction of the Residue Level on Processing.

In those cases where the assumption of tolerance level residues results in unsafe exposure, then the petitioner has the option of submitting data on food prepared for consumption. If these data indicate that trimming, cooking, peeling or processing, residues to the point that the ADI is not exceeded, data indicate that

washing, trimming, cooking, peeling or processing reduces residues to the point that the ADI is not exceeded, then the safety evaluation done by the Agency will be based on this lower level of residue. The tolerance, however, will still be set on the RAC as it travels in interstate commerce. Of course, if these data indicate that residues concentrate in some fractions while decreasing in others, both the higher and lower residue levels will be used in the safety evaluation. The Agency will also take into account the wide variation in techniques used to prepare food. For example, if cooking destroys the residue on a vegetable, the Agency will use the lower limit of detection in the cooking study as the residue level for cooked vegetables. The Agency will also use the consumption of uncooked vegetables and the tolerance level to estimate the exposure from uncooked vegetables. As noted above, if significant alteration in the nature of the residue could occur on processing, then a radiolabeled study will be needed to determine the nature of the residue following processing.

(3) Meat, Milk, Poultry and Egg Feeding Studies.

Data must be submitted to show the level of residues that will result in meat (muscle, liver, kidney and fat), poultry, eggs, or milk. These data are needed whenever a pesticide is to be applied directly to livestock, residues occur on a feed or forage crop, or residues occur on any plant parts that could be used in animal feeds. Based upon the residue level in the feed item and the residue resulting in meat, milk, poultry, and eggs in these feeding studies, the use must be classified as specified in 40 CFR 180.6(a). Category 1 of Section 180.6(a) applies to cases where it is shown that residues will occur in animal products; Category 2 applies if there is a reasonable expectation of residues in animal products; and Category 3 applies if there is no reasonable expectation of residues. Since tolerances for residues in animal products are required when the use is judged to be Category 1 or 2, the animal feeding studies must not only show whether residues transfer, but may also need to serve as a a basis for setting appropriate tolerance levels for the animal products.

(i) Residues in feeds.

The compound(s) or residues fed should correspond, as closely as possible, to the aged residues found in the items of feed. The components of the residue to be determined should be those found to constitute the "total toxic residue" in the animal products as determined in the livestock metabolism study described in section 171-4b. The feeding study should include the level of intake expected (1x), plus two exaggerated levels of 3x and 10x. The 1x level should represent the worst case estimate of the potential livestock exposure based on the assumption of all components of the

feed having tolerance level residues. The exaggerated levels are especially important in judging a Category 3 use, as well as to cover possible future tolerances for the pesticide on additional feed items and allow estimation of whether residue levels in tissues vary linearly with the level in the feed. The required limit of detection of the method applied to the animal products will be related to the toxicity of the compound but should generally be on the order of 0.01-0.05 ppm. The dosage levels should be expressed in terms of concentration (parts per million) in the total ration (dry weight basis), so that the Agency can relate the dosage to that expected from the proposed use. It is also desirable to express the feeding level in terms of mg/kg body weight.

In selecting the dosage levels based on total rations, the petitioner should take into account the proportion in the diet of the feed item bearing the residue. Table II should be used as a guide in determining the proportion of the diet of the various feed items. For example, dried citrus pulp may in some circumstances comprise up to 20% of the total ration (dry weight basis) of dairy cows. If a tolerance of 5 ppm of a given pesticide were proposed on dried citrus pulp, the total diet (dry weight basis) should be fortified at the 1 ppm level to reflect the expected level of intake (1x). If tolerances for other feed items could also be fed in combination with citrus pulp, the contribution from these feed items should also be added in. As noted, two dosages at exaggerated levels are also required, preferably three-fold and ten-fold or higher where not precluded by toxicity of the pesticide.

Separate feeding studies are required for a ruminant and poultry whenever residues occur on the feeds of these classes of livestock, or direct animal treatment is proposed. The species of choice for these feeding studies are the cow and chicken. A swine feeding study may be required for major swine feeds depending on the likelihood for residue accumulation in animal tissue. A swine study is required if direct application to swine is proposed as indicated in the next part (b) of this section.

In addition to establishing a baseline or blank in a pre-dosing period, control animals should be carried through the experiment with treated animals. This is highly desirable, since values for control animals have been observed to change during feeding studies. The number of animals carried at each treatment level, and as controls, will vary with the circumstances; but as a general rule each group in a cattle feeding study should comprise a minimum of three animals. For a chicken feeding studies, a minimum of 10 birds per group should be used. It is often advisable to have additional animals on test that can be used to determine the rate of decline of residues on the cessation of dosing, so that if residues above tolerance are found, data on the time necessary for residues to fall to the tolerance level are available.

The period of time during which the animals are kept on the treated feed will also depend on the individual case. Generally, animals should be kept on test until residues plateau in milk or eggs. If no residues are detected in milk or eggs, animals should be kept on test for four weeks.

(ii) Direct Animal Treatment.

When a pesticide is proposed for direct use on food animals, data are required to show the extent of residues incurred by the use. The experimental treatment should reflect as closely as possible the conditions under which the pesticide will be used commercially. Control animals should be carried along with treated animals. Factors such as whether sheep passing through a dip tank were freshly shorn or unshorn should be considered. Generally, separate studies should be carried out for each species of livestock to be treated. The data should also reflect treatment by several applicators.

When a pesticide may be applied in more than one type of formulation or by more than one mode of treatment, separate studies reflecting the usage or combination of usages proposed are required. However, data from dips or high pressure wetting sprays on cattle may be accepted in lieu of data from dust treatments but not vice versa. When the use of devices which permit unlimited access (e.g., backrubbers) are proposed, the experiment should be designed to assure the maximum exposure of the animal to the pesticide. Data reflecting exaggerated treatments are desirable.

(iii) Agricultural Premise Use Studies.

When the use of pesticides in agricultural buildings are such that restrictions cannot preclude the possibility of residues in meat, milk, poultry eggs or feed, residue studies should be carried out to determine the maximum conditions of exposure. The studies should reflect all possible residue transfer routes such as: (1) direct absorption (dermal or inhalation) from sprays, mists, or fogs with animals present; (2) direct consumption (e.g., by the animal licking surfaces treated with sugar base baits, pick up of bait granules by poultry, or contamination of feed, feed troughs, (or water troughs) and (3) direct contamination of milk from deposition on milking equipment, treatment of milk rooms, etc.. Separate studies are required for ruminants (cows), non-ruminants (swine) and poultry (chickens).

(iv) Meat, milk, poultry and egg sampling.

The tissues to be analyzed in a feeding study include all tissues that are used as a human food. If residues concentrate in a particular tissue such as fat, liver or kidney, then proportionately more of these tissue samples should be analyzed. Also, since muscle constitutes the majority of the food derived from livestock, proportionately more of these tissue samples should be analyzed.

Milk and egg samples should be taken twice daily. Eggs from birds within a dosage group may be pooled if necessary so that adequate sample weight is available for analysis and retained samples. Milk from animals within a dosage group should not be pooled so that data for individual animals are available. Enough of the pooled daily milk and egg samples should be analyzed to allow for a determination of trends in storage of residues with time. Animals should be slaughtered within 24 hours of the last dosing and tissue samples taken and frozen as soon as possible. Tissue residue level results from animals slaughtered long after cessation of dosing are not usable in estimating tolerances, and thus if this occurs, the feeding study will have to be repeated.

(4) Potable Water, Fish and Irrigated Crop Studies.

Any use of pesticides in or near aquatic sites may lead to residues in potable water, fish and shellfish, irrigated crops, and meat, milk, poultry and eggs. For each of these commodities, adequate data are needed to demonstrate both the nature of the residue and the level of residues resulting from the maximum proposed use. Because of the nature of aquatic uses, emphasis must be placed on the use of practical use restrictions which will be followed by the applicator.

The design of the aquatic pesticide studies to demonstrate the fate of the pesticide in the aquatic environment must be directly related to the restrictions imposed on the use. For example, use in impounded bodies which are completely under the control of the user may be subject to practical label restrictions that would preclude livestock watering, fishing, or use for drinking or irrigation for a specified time period after treatment. On the other hand, such restrictions would not be practical for use of a pesticide in a river system.

In the latter type of use, restrictions against treatment within a given distance of potable water intakes are considered practical. In general, separate and distinct protocols will be required for still waters (lakes, ponds), flowing water, irrigation conveyance systems, and tidal estuaries. The fate of the compound must be demonstrated with respect to rate of dispersion downstream,

degradation, volatilization, or sorption by plants or hydrosoil. Degradation products in water should be identified and may need to be quantified.

Experiments to show possible residues in crops irrigated with treated water may utilize the crop grouping scheme 40 CFR 180.34(f). Residue data for representative crops in each crop group are normally required. If it has been determined that residues are likely to occur in water when it could be ingested by livestock, animal feeding studies must be carried out as described previously.

Fish metabolism studies are required when fish may be exposed to the pesticide or its degradation products. If no ^{14}C is detected in fish in a static metabolism study then the following fish residue studies are not required. Shellfish residue studies will however still be required.

The fish and shellfish residue studies may be of various types, depending on the aquatic system involved. Controlled exposure for appropriate time intervals may be carried out under static or dynamic conditions in aquaria, or the specimens may be exposed in natural sites if the treated area can be isolated, such as by cages. Field studies under natural conditions are preferred. Samples for analyses should reflect the fish commodity definition in the Pesticide Analytical Manual, Volume I. The proposal for tolerances in fish should be expressed on the basis of the edible portion. For fish, residue data are needed for both bottom feeders, (e.g., catfish) and predators, (e.g., bass); for shellfish, data are needed for both molluscs (e.g., clams, oysters) and crustaceans (e.g., shrimp, crabs). If use in estuarine areas is planned, data on whole fish protein concentrate, and smoked, canned, or other processed fish products are needed to determine whether a Food Additive Regulation is necessary.

Potable water is defined as any water at such time as it enters a public drinking water system whether or not it receives any treatment or filtering. Data must show the highest level likely to occur in water at any time it may be used for drinking purposes. Data showing the extent to which the compound is removed or reduced in specific water treatment processes are desirable. However, if safety of the use is predicated on removal or reduction of the residue in water by a commercial treatment process, there must be practical restrictions limiting use to bodies of water that will necessarily receive the processing before consumption of the water. For example, use to control weeds in reservoirs could be limited to reservoirs which flow into specific water treatment facilities.

(5) Food Handling Establishment Use Studies.

Studies must be conducted to determine residues in food or feed resulting from treatment of food/feed handling establishments* with residual insecticides** (Asterisked terms are defined below and in Federal Register Notice Vol. 38, No. 154, Friday,

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* A food handling establishment is an area or place other than a private residence in which food is held, processed, prepared and/or served.

a. Nonfood areas of food handling establishments include garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling).

b. Food areas of food handling establishments include areas for receiving, serving, storage (dry, cold, frozen, raw), packaging (canning, bottling, wrapping, boxing), preparing (cleaning, slicing, cooking, grinding), edible waste storage, enclosed processing systems (mills, dairies, edible oils, syrups).

** Nonresidual insecticides are those products applied to obtain insecticidal effects only during the time of treatment and are applied either as space treatments or contact treatments.

a. Space treatment is the dispersal of insecticides into the air by foggers, misters, aerosol devices or vapor dispensers for control of flying insects and exposed crawling insects.

b. Contact treatment is the application of a wet spray for immediate insecticidal effect.

Residual insecticides are those products applied to obtain insecticidal effects lasting several hours or longer and are applied as a general, spot, or crack and crevice treatments.

a. General treatment is application to broad expanses of surfaces such as walls, floors, and ceilings or as an outside treatment.

b. Spot treatment is application to limited areas on which insects are likely to occur, but which will not be in contact with food or utensils and will not ordinarily be contacted by workers. These areas may occur on floors, walls, and bases or undersides of equipment. For this purpose, a "spot" will not exceed 2 square feet.

c. Crack and crevice treatment is application of small amounts of insecticides into cracks and crevices in which insects hide or through which they may enter the building. Such openings commonly occur at expansion joints, between different elements of construction, and between equipment and floors. These openings may lead to voids such as hollow walls, equipment legs and bases, conduits, motor housings, junction or switch boxes.

August 10, 1973). Establishments to be treated will be typical commercial operations selected from among the various types listed under each of the categories shown in Table I. Data obtained from tests conducted in two different types of establishments in each category will normally be adequate for clearance of the insecticide for use in all types of establishments defined by the category of which the test establishment is a part. Careful judgment will have to be applied in selecting the types of establishments to be tested as well as the number of tests necessary in order to ensure adequate representation of that category. More than two types of establishments may require testing as the individual case indicates. Existing sanitation programs and practices, as well as the type of building construction (wood, cement block, etc.) at a plant site, are important factors that should be considered. Usage will normally involve application of the insecticide as a general, spot, or crack and crevice treatment; and will include both nonfood and food areas of the establishment used as the test site. Acceptable results from a test of the most rigorous type of treatment (general > spot > crack and crevice) will preclude need for residue tests involving less rigorous treatments; and will allow clearance of the insecticide for use by the less rigorous method(s). Labeling must specify that treatment of establishments will be performed in accordance with proposed labeling by a certified (or otherwise qualified) pest control operator whose work for the past year has included treatment of establishments in the same category.

The experiment should be designed to reflect all possible avenues of contamination, taking into account the physical and chemical properties of the pesticide; proximity of foods and protective barriers as may be specified in the regulation; mode of application; and use restrictions.

Considerations should be given to at least the following residue transfer routes where applicable:

(1) Direct deposition of spray droplets on foods, direct absorption of fumigant, airborne dust particles;

(2) Volatilization of residual deposits and subsequent absorption into foods;

(3) Direct transfer of residues from treated surfaces (countertops, cupboards, utensils, packaging materials, etc.);

(4) Volatilization with condensation on surfaces where food is subsequently placed;

(5) Leakage or weeping of chemical from devices or impregnated materials, hung in food establishments for insect control;

(6) Transfer of pesticide through permeable barriers (e.g., from impregnated shelf papers to packaged food);

(7) Tracking of residues from bait stations or sprayed areas to foods or food contact surfaces by rodents or insects, or contamination from fallen insects;

(8) Deposition of solid or crystalline chemicals from repeated sprays on ceilings over food handling areas;

(9) Distribution of vapors, droplets, or particulate matter through forced ventilation systems (central air conditioning, duct heating systems);

(10) Distribution of residues in continuous process food operations from treatment of ends and tailings, conveyor lines, boots, etc., when operation is shut down (e.g., flour mills).

Many sources of contamination may be eliminated (or greatly diminished) as practical sources of contamination through use restrictions, variations in the mode of application, type of establishment treated or nature of the product or formulation. Data should be submitted to establish the relative importance of these factors on the levels of residue which may be expected to result from the pesticidal application. Experiments should be conducted by analyses of representative foods subjected to exposure by any of the above routes which are potential avenues of contamination.

The selection of samples for analyses in the more specialized uses, e.g., flour mills, would be apparent. In the more generalized exposure situations, e.g., grocery stores, it is suggested that the selection of samples for analyses represent a range of foods such as an oily food (butter), baked cereal products, beverages, raw and processed meats, and fresh fruits and vegetables (lettuce).

In order to demonstrate the residues resulting from the wide variation of conditions anticipated in actual situations, and to gauge the potential for misuse, the experiment should include some exaggerated exposure. This might include spraying at a 2x rate, exposure of foods for longer periods than might normally be expected, or even exposure of some foods when there is a restriction to cover foods when treating.

For certain uses (notably the devices of the automatic dispenser and impregnated resin strip type), the total exposure would include inhalation as well as oral ingestion of residues on foods. In these cases, the experiment should include some determination of concentration in air under representative conditions.

§171-5 Practical Methods for Removing Residues That Exceed Any Proposed Tolerance. (Section E of a petition)

Except in certain specialized pesticide applications, the tolerances are set at levels that are adequate to cover residues that are likely to result from a proposed use without any special processing of the commodities to reduce residues to the tolerance level. In a few pesticide uses, however, the judgment of safety is predicated on the reduction of residues by aeration of fumigated commodities or other processes intended to reduce residues. In these cases, section E should include a discussion of how the tolerance level residues, which are higher than a safe level, are reduced to a safe level. The data on which these determinations must be based is discussed in Section 171-4(c)(2)(iv).

§171-6 Proposed Tolerances. (Section F of a petition)

Tolerances should be proposed in terms that best represent the total toxic residues on the raw agricultural commodity, whether it be the parent pesticide or altered forms of it, or both. The proposed tolerance should not be based on an "average residue" value but should be large enough to include any residue values which could be reasonably expected based on the available data.

It should not be larger than is needed for the proposed use although some limited accommodation to this rule may be necessary in the interest of avoiding an inordinate multiplicity of tolerance levels for a single pesticide on a number of different crops. Analytical methods will commonly determine one or more conversion products along with the parent compound when the method is based on measurement of a chemical moiety common to all. In such cases, it may be appropriate to propose combined tolerance for all of the compounds calculated as the parent compound, toxicological considerations permitting.

The petitioner should consider whether the proposed tolerance can be made compatible with Maximum Residue Limits (MRL's) established by the Codex Alimentarius Commission (an organization set up under the auspices of the United Nations to facilitate international trade) or the tolerances established by Mexico or Canada. The tolerance comparison should include compatibility of both the numerical level proposed and the residue definition (i.e., the metabolites included in the tolerance).

An exemption from the requirement of a tolerance may also be proposed when appropriate (See Section 171-8). When an exemption is proposed, data must be presented to show the level of residues to be expected. Other chemistry data requirements, in general, parallel those for numerical tolerances.

In the case of Food Additive Regulations covering the use of pesticides in food handling establishments, it is contemplated that the regulation may or may not include a numerical tolerance on foods. In either case, the proposed regulation should specify the conditions of use of the pesticide. The determination of whether a numerical tolerance is needed will be based on the toxicity of the residue and the level of possible contamination.

§171-7 Reasonable Grounds in Support of the Petition. (Section G of a petition)

The petitioner should present the rationale of how the residue data support the proposed tolerance. The presentation should include brief discussions on the adequacy of the analytical method with respect to sensitivity and determination of the total toxic residue; an explanation of any aberrant residue values reported; an explanation for the omission or substitution of requirements set forth in these Guidelines; and any other residue considerations pertinent to the proposed use. Where appropriate, a discussion should be furnished on the status of other components of the formulations.

§171-8 Exemptions from the Requirement of a Tolerance.

(a) Active Ingredients. Exemptions from the requirement of a tolerance are appropriate for pesticides for which no enforcement action can be anticipated. Since an exemption from the requirement of a tolerance means that there is no limit on the level of residue that could occur, exemptions are limited to relatively non-toxic pesticides. Examples of active ingredients for which an exemption is appropriate are acetic acid and sulfur. Exemptions from the requirement of a tolerance for an active ingredient should be requested by submission of a petition. Normally, the only information/data needed in such a petition are the data from Sections A, B, E, F, and G. The normal residue chemistry data requirements in Section D will be waived for toxicologically-innocuous active ingredients, except possibly for the requirement of an analytical method if needed for enforcement purposes.

(b) Inert Ingredients. Inert ingredients of pesticide formulations have been determined to be pesticide chemicals within the meaning of the Act and are subject to the Pesticide Amendment (Section 408) of the FFDC Act. A large number of these inert ingredients have been exempted from the requirements of a tolerance (40 CFR Section 180.1001). Requests to add other adjuvants should be submitted as petitions for exemption or as a letter to the Director of the Registration Division, Office of Pesticides Programs. Data requirements for inerts

will not ordinarily be as extensive as for active ingredients. However, an analytical method may be required and a basis for estimation of the level of residues likely to result must be provided. Limitations on the use may be imposed in the exemption regulation. Any clearances of the inert ingredient by the Food and Drug Administration as a food or feed additive should be referenced. The amount of residue chemistry data needed for the exemption of an inert ingredient will vary with the nature of the chemical. The minimum information required are a description of the identity of the chemical and the possible uses involved. If the inert ingredient cannot be deemed toxicologically-inoccuous, then additional data will be required. In some case the full data requirements described for active ingredient tolerances will be required, while in other cases only an analytical method and residue data for representative crops will be required. The amount of data required will depend on the toxicity of the chemical and the use restrictions imposed.

§171-9 Tolerances for Foreign Uses.

Foreign uses are not subject to registration requirements. However, proposals for tolerances for residues in any imported foods or feeds should be submitted under Section 408(e) of the Federal Food, Drug, and Cosmetic Act. Tolerances proposed in conjunction with requests for domestic registration are submitted under 408(d) of the Act. Petitions submitted under 408(e) should contain the same types of information, including sample labelling, and data as those submitted under 408(d). In addition, the petition should briefly discuss any controls regulating the use of pesticides in the country in which the pesticide will be used and some evidence that the requirements for use in the foreign country have been met.

§171-10 Rotational Crops Tolerances.

The requirements for rotational crop tolerances are included in "Tolerance for Pesticide Residues in Rotational and Follow-up Crops, Meat, Milk, Poultry and Eggs, and for other Indirect Inadvertent Residues," FR Vol 40, Vol 8, Tuesday, January 13, 1981. Section 165 of these guidelines (Environmental Fate, Rotational Crop Data Requirements) should also be consulted concerning when petitions, and tolerances, for rotational crops are required.

As noted in the FR notice cited above, the residue chemistry data requirements for a petition for a tolerance in rotational crops are the same as those required for a conventional tolerance. However, it should be noted that for rotational crop tolerance petitions, Section B must contain directions for use on the target

crop and limitations as to which, and when, crops may be planted following harvesting or destruction of the target crop. The limitations in the number of crops and timing of planting will determine the amount of data needed for rotational crop tolerances. If no limitations on rotational crops are added to the label, then residue data for representative crops in the crop grouping scheme 40 CFR 180.34(f) will be required before rotational crop tolerances can be established.

The design of the residue field trials must of course also match the restrictions included in the Section B. For example, the restrictions could indicate that soybeans may be planted 14 days after corn has been planted, if the corn germination is poor. The residue field trial should then consist of application to the soil planted to corn, followed by planting of soybeans 14 days later and analysis of soybeans as normally required.

Eighteen months is the longest planting interval which is considered practical. If residues persist in the soil past 18 months, then rotational crop tolerances for representative crops in the crop grouping scheme will be required. The field trial data in this case should include data on the uptake of residues 18 months after application to the parent crop by all representative crops in the crop grouping scheme.

Rotational crop tolerances will be distinguished in the CFR from parent crop tolerances. The publication of a rotational crop tolerance will not allow for registration of use under FIFRA on the rotational crop. The purpose of the rotational crop tolerances is only to allow for the presence of residues of persistent pesticides that occur in crops other than the target crop.

§171-11 Tobacco Uses.

Use of a pesticide on tobacco does not require a tolerance or an exemption from the requirement to obtain a tolerance. Nonetheless, data are needed to assess the exposure of man to the residue remaining at the time of use of the tobacco. The data required include a residue profile for the tobacco and its smoke.

This residue profile must include the active ingredient and all significant plant metabolites of the active ingredient, translocated degradation products from soil, and photodegradation products. Radioisotopic techniques will normally be required to identify the significant components of the residue. If residues at 0.1 ppm or more are detected, analytical methods must be developed.

Data from the following studies must be submitted to show conclusively the level of residue likely to result from the use of the pesticide:

(1) Total residues on green freshly-harvested tobacco. If residues at 0.1 ppm or more are detected, the determinations of the next paragraph of this section are required.

(2) Pyrolysis products derived from the active ingredient must be characterized.

§171-12 Food Use/Non-Food Use Determination Data Requirements.

In some cases residue chemistry data are needed to determine whether a proposed use is a food use or a non-food use. The general criteria for food use/non-food use determinations is that if residues could occur in foods or feed, then the use is a food use and a petition for tolerance/exemption from tolerance is required. In some cases this determination can be made based on the nature of the site to which the pesticide is to be applied. Thus application to non-cropland is considered a non-food use. In other cases the distinction is not as clear. For example, baiting with a rodenticide around the borders of cropland or in a tamper-resistant bait box within cropland would be considered a non-food use, but applying the bait directly to the crop would be considered a food use.

For the following types of uses, the food use/non-food use determination will be based on the results of the data described in each section. Registration for these types of uses will not be granted until the necessary data have been submitted to the Agency and found acceptable.

(a) Seed Treatments.

This includes cases where seed is treated either by the seed company (and dyed according to the Seed Act) or by the farmer (planting box or hopper treatments).

In order for a seed treatment to be considered a non-food use, data from a radiotracer study must be available showing no uptake of residues (activity) from treated seed into the aerial portion of the growing crop.

If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances.

(b) Crops Grown for Seed Only.

These crops would qualify as non-food uses provided there is no likelihood of residues in crops grown from the harvested seeds. Factors affecting this include the level of residues on the harvested seed, the half-life of seed residues, the weight of the seed in relation to that of the subsequent crop and the amount of residue uptake from the seed into the aerial portion of the crop.

On the other hand, uses on crops where the seed itself is a major raw agricultural commodity, (such as corn, sorghum, soybeans, small grains and sunflowers), are considered to be food uses. In these cases, seeds from treated crops could not be distinguished from untreated crops and could be diverted to human and animal comsumption.

Alfalfa and clover grown for seed cannot be considered a non-food use because of the economic importance of alfalfa and clover hay. Subsequent cuttings for hay would be taken regardless of label restrictions. Also, because of the increasing importance of alfalfa sprouts as a human food item, use on alfalfa grown for seed only cannot be considered a non-food use.

Dessication uses for clover grown for seed will be considered non-food uses because the dessication renders the hay unfit for consumption by livestock.

(c) Fallow Land. Use of a pesticide on fallow land requires data indicating whether residues persist in soil long enough for uptake by crops. See the Environmental Fate Section for the design of soil persistence studies. Fallow land uses must include a time limitation on planting to food/feed crops or tobacco. Eighteen months is the longest time interval deemed practical for a fallow land use restriction. If residues persist in soil for the length of the time of planting limitation, or 18 months (whichever is shorter), then a petition for tolerance for all crops which could be planted on the fallow land will be required.

(d) Non-bearing Crop Uses. Application of a pesticide to a non-bearing food or feed crop will be considered a nonfood use only if data are available to demonstrate that no detectable residues occur in the crop at the first harvest. Non-bearing crops are perennial crops that will not produce a harvestable RAC during the season of application. Thus the label must contain a restriction against harvesting during the season of application. If residues are detected, then a petition for tolerance with the full range of

residue chemistry data requirements will be needed before a tolerance and registration will be granted.

§171-13 Submittal of Analytical Reference Standards.

To avoid delay in processing petitions for new pesticides, 2 gram samples of purified analytical standards for the pesticide and/or its principal degradation products or metabolites should be submitted to the Pesticide and Industrial Chemicals Repository (MD8), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, USA.

The letter of transmittal should include the assay of the standards, the analytical methods used, a statement of principal impurities, purification procedures, storage requirements and special precautions for safe handling. A copy of the transmittal letter should be inserted in Section A of the petition. Larger quantities of standards are usually required once the tolerance is established. Replacement of standards may be required periodically should decomposition occur in storage. For non-acutely toxic metabolites which are difficult to synthesize, quantities less than 2 grams will be acceptable.

§171-14 Special Considerations for Temporary Tolerance Petitions.

A temporary tolerance may be established in conjunction with an Experimental Use Permit (see Section III of these Guidelines).

A petition for a temporary tolerance should specify the amount of pesticide which will be used under the conditions of the experimental permit, the crop acreage which will be treated, and the geographical areas where the treatments will be made.

The chemistry data requirements for permanent tolerances will in general apply to petitions for temporary tolerances except that method trials will not be conducted and the metabolism and residue data need not be as extensive. Whether the latter exception is to be made will depend on the toxicity of the pesticide or possible degradation products and/or metabolites, the amount of acreage to be treated, the importance of the food or feed commodity, and similar considerations. It is assumed that data will be obtained while the experimental permit is in effect and will be made available to the Registration Division.

§171-15 Presentation of Residue Data.

Individual analyses, not average results, should be reported. The data should include blank values and uncorrected values for the treated samples. It should be indicated whether corrections have been made for blanks and recoveries. When GLC is the method of analysis, corrections should not be made for blanks due to discrete peaks (at the retention time of the pesticide sought) in the chromatograms of untreated controls.

It is preferable to summarize the data in tables showing crop, residue found, dosage, interval from treatment, number of applications made, and formulation used. However, the tabulated data should be keyed for ready reference to the raw data and sample history sheets. The sample history sheets should note rainfall, sample treatment (washed, brushed, trimmed, etc.), sample collection and analysis dates, storage conditions, and other factors which might affect the residue levels.

The raw data should include standard curves, optical absorbance readings, or copies of appropriately labeled gas chromatograms. It is desirable that at least some of the chromatograms show the analyst's sample dilution factors, sample equivalent injected, and the way in which GLC peaks were quantitated. Photographs of thin-layer chromatography plates, paper chromatograms, or radioautographs of plants treated with labeled pesticides should be furnished when such evidence is necessary for the evaluation of the data.

A statistical treatment of data may be used to express the precision and accuracy of the analytical results when sufficient data make such treatment valid. The null hypothesis technique is useful in calculating the confidence level at which a set of values from control samples do not differ significantly from a set of values from treated samples. A graphical representation of residues versus time (decline or dissipation rate curves) is also desirable. This is usually plotted on semi-log coordinates with time (days after treatment) as the linear function.

§171-16 Translation of Data.

Data on tissue storage in rats, dogs, or other small animals used in toxicology studies will not be accepted in lieu of residue data on livestock. Data will not be translated from other meat animals to poultry. However, within the poultry group, data on chickens will usually be accepted in lieu of data on turkeys. Data on residues in milk from dairy cows will usually apply as well to dairy goats. Because of the higher fat/body weight ratio in hogs, data on concentration of pesticides in the body fat of hogs may not be applicable to goats or other animals of lower total body fat content.

In some cases it may be possible to combine the radioactive livestock metabolism study and the livestock feeding study. However, this is usually not desirable because of the need to dose more animals for longer periods of time with radiolabeled material.

A list of similar crops for which residue data may be translated is given in the Regulations, 40 CFR180.34(e). Pesticides which are absorbed into the plant or animal may be excluded from this translation of residue data [Section 180.34(c)].

The crop grouping scheme described in CFR 40 180.34(f) includes information on crop group tolerances. Utilizing the crop group concept described can allow for tolerances on all crops in a group of related crops based on data only for the representative crops in a group.

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Dr. Robert J. Hummel and Dr. Charles L. Trichilo and Messrs. Robert S. Quick, George Beusch, and Donald Reed reviewed and made significant contributions to the development of Subdivision O.

TABLE I

Categories and Representative Types of Food Handling Establishments.

Category	Representative Types
Food Service[1] Establishments	Restaurants, Cafeterias, Taverns, Delicatessens, Mess Halls, School and Institutional Dining Areas, Hospitals, Mobile Canteens, Vending Machines, Groceries and Markets.
Manufacturing[2] Establishments	Candy Plants, Ice Cream Plants, Spaghetti or Macaroni Plants, Food Mix Plants, Breaskfast Cereal Plants Bakeries, Breweries, Wineries, Soft Drink Bottling Plants, Pizza Plants.
Processing[3] Establishments	Meats, Poultry, and Seafood Slaughtering and/or Packing Plants, Dairies and Dairy Products Plants, Spice Plants, Edible Fats and Oils Plants, Fruit and Vegetable Canneries, Pickle Factories, Beverage (Coffee, Tea) Plants, Frozen Fresh Food Plants, Grain Mills.

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[1] Any food handling establishment whose principal business involves the sale of food directly to the consuming public. The manufacture and/or processing of food by such an establishment is only incidental to achieving its principal business objective.

[2] Any food handling establishment whose principal business involves the production and/or packaging of man-made foods which are normally intended for sale through or by food service establishments. Such foods are generally composed of two or more ingredients which have been altered in such a manner as to change their basic identity.

[3] Any food handling establishment whose principal business involves the the upgrading and/or preservation of raw agricultural commodities in such a manner as to maintain their essential identity. Such establishments may sell their product directly to the consuming public and/or food service or food handling establishments.

TABLE II

Raw Agricultural Commodities and Feeds Derived From Field Crops

CROP	RAC	PROCESSED COMMODITIES	FEED	PERCENT OF LIVESTOCK DIET[1]					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Alfalfa	Forage	Meal	Forage(G)[2]	50	80	NU[3]	NU	NU	NU
	Seed		Seed	30	10	20	20	10	10
	Hay		Hay	25	80	NU	NU	NU	NU
			Meal	25	80	5	5	50	5
Almond	Nutmeat								
	Hulls		Hulls	25	25	NU	NU	NU	NU
Apples	Fruit	Pomace, wet							
		Pomace, dry	Pomace, dehy	50	25	5	NU	NU	NU
		Juice							
Apricots	Fruit								
Artichoke	Fresh								
Asparagus	Fresh								
Avocados	Fresh								
Bananas	Fresh								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Barley	Grain Forage Hay Straw	Germ Milling products	Grain Forage(G) Hay(G) Straw(G)	80 20 25 10	50 40 60 10	50 NU NU NU	50 NU NU NU	80 NU NU NU	40 NU NU NU
Bean	Seed and pod, succulent Seed, dry Vine Hay	Cannery residue	Seed Vine(G) Cannery residue Hay(G)	20 20 20 20	20 35 20 35	10 NU NU NU	15 NU NU NU	25 NU 10 NU	20 NU 10 NU
Beet, garden	Root Greens								
Blackberries	Berry								
Boysenberry	Berry								
Blueberry	Berry								
Broccoli	Fresh								
Brussels Sprouts	Fresh								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Buckwheat	Grain Forage Hay Straw	Bran Milled products	Grain	50	50	70	50	80	90
			Forage(G)	25	70	NU	NU	NU	NU
			Hay(G)	25	60	NU	NU	NU	NU
			Straw(G)	10	10	NU	NU	NU	NU
			Milled bypdts	25	25	10	5	10	5
Cabbage	Fresh, with wrapper leaves Fresh, w/o wrapper leaves								
Cacao bean	Bean	Roasted bean Cocoa powder Chocolate							
Cantaloupe	Fresh								
Carob bean	Bean								
Carrot	Root								
Casaba	Fruit								
Cauliflower	Fresh								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Celery	Fresh								
Cherries	Sweet Sour								
Chicory	Leaves								
Citrus	Whole fruit	Dried Pulp Peel Oil Molasses Juice	Pulp, dehy Pulp, wet Molasses	33 20 15	33 10 10	NU NU NU	NU NU NU	1 10 NU	1 10 NU
Clover	Fresh Hay		Fresh Hay	25 25	50 80	NU NU	NU NU	10 NU	5 NU
Cocoanut	Cocoanut (meat and liquid combined)	Copra (dried meat) Oil Meal	Copra Meal	15	15	15	10	NU	NU
Coffee	Green bean	Roasted bean Instant							

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Collards	Greens								
Corn, field	Grain Forage Silage Fodder	Crude oil Refined oil Milled products	Grain Forage Silage Fodder	80 25 25 25	50 10 10 10	70 NU NU NU	70 NU NU NU	80 NU NU NU	85 NU NU NU
Corn, pop	Grain Forage Fodder		Forage(G) Fodder(G)	25 30	10 50	NU NU	NU NU	NU NU	NU NU
Corn, sweet	Sweet corn Forage	Cannery waste	Forage(G) Cannery waste	25 30	10 50	NU NU	NU NU	NU NU	NU NU
Cotton	Seed Forage	Meal Hulls Soapstock Crude oil Refined oil	Meal Seeds Hulls Soapstock Forage(G)	15 25 15 5 20	15 20 5 5 40	10 NU NU 5 NU	3 NU NU 5 NU	5 10 NU 5 NU	5 10 NU 5 NU
Cowpeas	Seed Hay Forage		Seed Hay Forage	25 20 30	70 20 100	10 NU NU	10 NU NU	10 5 NU	10 5 NU
Crabapple	Fruit								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Cranberry	Berry								
Crenshaw	Fruit								
Cucumbers	Fruit								
Currants	Fruit								
Damsons	Fruit								
Date	Fruit								
Dewberries	Berry								
Eggplant	Fruit								
Elderberry	Berry								
Escarole	Fresh								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING
Figs	Fresh	Dried							
Flax	Seed	Meal (linseed)	Meal	15	25	3	3	5	5
	Straw	Hulls	Straw(G)	10	10	NU	NU	NU	NU
			Hulls	20	10	NU	NU	10	10
			Seeds	10	10	3	3	20	20
Garlic	Bulb								
Gooseberries	Berry								
Grapes	Fruit	Raisin							
		Pomace, wet	Pomace, wet	30	20	3	3	10	10
		Pomace, dry	Pomace, dry	30	20	5	5	20	20
		Raisin waste	Raisin waste	10	10	NU	NU	NU	NU
		Juice							
Grass	Fresh		Fresh	75	70	NU	NU	NU	NU
	Hay		Hay	70	70	NU	NU	NU	NU

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Guar	Seed Forage	Milled products	Seed Forage(G) Meal	10 20 10	10 40 15	15 NU 15	15 NU 15	10 NU 10	10 NU 10
Hops	Fresh	Dried Spent hops	Spent hops	5	5	NU	NU	NU	NU
Horseradish	Root								
Huckleberries	Berry								
Jerusalem artichoke	Root								
Kale	Fresh								
Kiwi	Fruit								
Kohlrabi	Fresh								
Kumquats	Fruit								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Leeks	Stalk								
Lentils	Fresh								
	Forage		Forage	20	35	NU	NU	NU	NU
	Hay		Hay	20	35	NU	NU	NU	NU
Lespedeza	Fresh		Fresh	80	80	NU	NU	NU	NU
	Hay		Hay	70	70	NU	NU	NU	NU
Lettuce	Fresh, with wrapper leaves								
	Fresh, w/o wrapper leaves								
Loganberries	Berry								
Lupine									
	Forage		Forage	50	80	NU	NU	NU	NU
	Hay		Hay	25	80	NU	NU	NU	NU
Mangoes	Fruit								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Melons	Fresh								
Millet	Grain	Milled products	Grain	25	25	20	50	50	25
Mint	Hay	Spent hay Oil	Spent hay	25	60	NU	NU	NU	NU
Mungbean	Bean	Sprouts							
Mushroom	Head & stem								
Mustard	Greens	Seeds	Seeds	10	5	15	15	10	10
Nectarines	Fruit								
Nuts	Nutmeat								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Oats	Grain	Milled products	Grain	20	50	25	20	80	40
	Hay		Hay(G)	25	60	NU	NU	NU	NU
	Straw		Straw(G)	10	10	NU	NU	NU	NU
	Forage		Forage(G)	20	40	NU	NU	NU	NU
	Hulls		Hulls	5	NU	NU	NU	NU	NU
Okra	Fruit								
Olives	Fruit	Oil							
Onion, bulb	Bulb								
Onion, green	Whole plant								
Papayas	Fruit								
Parsley	Leaves								
Parsnip	Roots		Roots	30	30	5	1	10	10

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Passion fruits	Fruit								
Pawpaws	Fruit								
Peaches	Fruit								
Peanuts	Nutmeat Vines Hay Hulls	Meal Crude oil Soapstock Refined oil	Meal Vines(G) Hay(G) Hulls Soapstock	15 20 25 5 5	25 40 60 Nu 5	10 NU NU NU 5	10 NU NU NU 5	10 NU NU NU 5	10 NU NU NU 5
Pears	Fruit								
Peas	Seed and pod, succulent Vines Straw Dried seed		Seed, dehy Vines(G) Hay (G)	30 25 25	25 40 40	10 NU NU	40 NU NU	20 NU NU	20 NU NU
Peppermint	Hay	Oil Spent hay	Spent hay	25	60	NU	NU	NU	NU

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Peppers	Fruit								
Pimentos	Fruit								
Pineapple	Fruit Forage	Bran Juice	Bran Forage(G)	40 20	40 40	NU NU	5 NU	20 NU	20 NU
Pistachio	Nutmeat								
Plantain	Whole fruit								
Plum	Fruit	Prune							
Potato	Tuber	Granules Chips Dried	Cull potatoes	30	30	7	20	50	50
Pumpkin	Fruit								
Quinces	Fruit								
Radish	Fresh								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Rape	Seed	Meal Oil	Meal	15	10	7	2	5	5
Raspberry	Berry								
Rhubarb	Fresh								
Rice	Grain Straw	Polished rice Hulls Milled products	Grain, w/hulls Straw(G) Milled bypdts	25 10 25	25 NU 25	40 NU 40	20 NU 20	NU NU NU	NU NU NU
Rutabagas	Roots								
Rye	Grain Forage Straw	Milled products	Grain Milled bypdts Forage(G) Straw(G)	75 50 20 10	40 25 40 NU	5 5 NU NU	5 NU NU NU	20 NU NU NU	25 NU NU NU
Safflower	Seed	Meal Oil	Seed Meal	10 15	NU 20	10 10	5 5	NU 20	NU 20
Sainfoin	Forage Hay		Forage Hay	50 25	80 80	NU NU	NU NU	NU NU	NU NU
Salisfy	Fresh								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Sesame	Fresh								
Shallots	Fresh								
Sorghum, grain	Grain	Flour	Grain	80	40	60	60	80	90
	Forage		Fodder(G)	25	50	NU	NU	NU	NU
	Fodder	Milled pdts	Silage(G)	25	50	NU	NU	30	30
	Silage		Hay(G)	25	60	NU	NU	NU	NU
	Hay								
Sorghum, sweet (sorgo)	Seed	Syrup	Forage(G)	80	50	NU	NU	NU	NU
	Forage		Fodder(G)	80	50	NU	NU	NU	NU
	Fodder								
Soybean	Seed	Meal	Seed	10	25	20	50	20	20
	Forage	Hulls	Meal	25	25	30	20	20	20
	Hay	Soapstock	Hulls	20	10	NU	NU	10	5
	Straw	Crude oil	Ensiled	25	40	NU	NU	NU	NU
		Refined oil	Hay(G)	10	40	NU	NU	NU	NU
			Straw(G)	10	NU	NU	NU	NU	NU
			Forage(G)	20	40	NU	NU	NU	NU
			Soapstock	5	5	5	5	5	5
Spearmint	Hay	Spent hay	Spent hay	25	60	NU	NU	NU	NU
		Oil							
Spices	Fresh	Dried							

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Spinach	Fresh								
Squash	Fresh								
Strawberry	Fresh								
Sugar beet	Root Tops	Pulp, dehy. Molasses Sugar, refined	Leaves(G) Molasses Pulp,dehy.	20 20 25	20 10 30	NU 4 NU	NU 4 NU	NU 5 15	NU 5 5
Sugarcane	Cane Forage	Molasses Sugar, refined Bagasse	Molasses Bagasse Forage(G)	20 5 20	10 5 40	3 NU NU	4 NU NU	10 NU NU	10 NU NU
Sunflower	Seed Forage	Meal Hulls Oil, crude Oil, refined	Meal Meal, w/o hulls Forage(G) Hulls	30 15 20 5	20 25 40 5	15 15 NU NU	15 5 NU NU	10 10 NU NU	10 20 NU NU

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Tea	Leaves	Dried							
Tomato	Fruit	Pomace, wet Pomace, dry Puree Catsup Juice	Pomace, wet Pomace, dry	20 25	10 25	3 NU	2 NU	10 NU	10 NU
Trefoil	Forage Hay		Forage Hay	50 25	80 80	NU NU	NU NU	NU NU	NU NU
Turnip	Root Tops		Roots(G) Tops(G)	20 5	10 5	NU NU	NU NU	NU NU	NU NU
Vetch	Forage Hay		Forage Hay	20 20	60 40	NU NU	NU NU	NU NU	NU NU
Water cress	Fresh								
Watermelon	Fruit								

TABLE II (Continued)

CROP	RAC	PROCESSED COMMODITIES	FEEDS	PERCENT OF LIVESTOCK DIET					
				CATTLE		POULTRY		SWINE	
				BEEF	DAIRY	TURKEY & BROILERS	LAYING HENS	BOARS & SOWS	FINISHING ANIMALS
Wheat	Grain Forage Hay Straw	Milled products	Grain	50	50	70	50	80	90
			Forage(G)	25	70	NU	NU	NU	NU
			Hay(G)	25	60	NU	NU	NU	NU
			Straw(G)	10	10	NU	NU	NU	NU
			Milled bypdts	25	25	10	5	10	5
Youngberries	Berry								

(1) Maximum percent of diet on a dry weight basis
(2) NU - Not Used
(3) G - Under control of the grower and thus subject to label restrictions against feeding